

AF 11744

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	)	Examiner: M. CHORBAJI
B. SCHINDLY, et al.	)	
	)	Art Unit: 1744
Serial No.: 09/314,497	)	
	)	Conf. No: 5279
Filed: May 19, 1999	)	
	)	
For: <b>FLOW THROUGH CHEMICAL</b>	)	
<b>INDICATOR FOR</b>	)	
<b>MEASUREMENT</b>	)	
<b>OF ACTIVE BIOCIDAL</b>	)	
<b>AGENTS</b>	)	
	)	
Date of Last Office Action:	)	
April 22, 2003	)	
	)	
Attorney Docket No.:	)	Cleveland, OH 44114
MEDZ 2 01012	)	June 20, 2003

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37 CFR § 1.93(b)(2) ELECTION

Mail Stop:  
Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR § 1.93(b)(2) and MPEP § 1208.02, the applicants hereby elect to reinstate the appeal.

The applicants express their appreciation to Examiner Chorbaji for reopening prosecution on the merits. The applicants would normally avail itself of every opportunity to resolve the patentability question before the Examiner. However, the heart of the disagreement with the Examiner concerns interpretation of the references, particularly the lack of motivation to combine the two cited references. The Examiner has issued five Office Actions (including the most recent one reopening prosecution) and the applicants have filed four responses and conducted a telephone interview to argue for patentability. After due consideration, the applicants are forced to conclude that an issue has been reached with the Examiner and submitting further amendments would be fruitless.

As set forth in greater detail on the accompanying Brief, the Examiner is relying on a combination of Minerovic and Ignacio. Minerovic discloses a source of sterilant concentrate, particularly a unit dose of powdered reagents which are mixed with several liters of water to create a liquid sterilant that is sent to the sterilization chamber or region. Ignacio is directed to a chemical indicator which is placed in the sterilization chamber, preferably attached as a label to individual items to be sterilized or to a seal for sealing packaging, such as a water-permeable microbial contamination-impermeable wrapper, in which the instrument is placed prior to and during the sterilization cycle (col. 9, lines 55-58). The Ignacio chemical indicators, like conventional chemical indicators, provide an indication of whether the item being sterilized has been subject to conditions which are reasonably expected to cause sterilization, such as a combination of concentration, time, and temperature (col. 1, lines 18-22). This assures that an individual instrument was not located in a "cold" spot where it was subject to too little sterilant flow, a portion of flow with low sterilant concentration, improperly stacked or positioned relative to other objects which partially blocked its receipt of sterilant, or any of the innumerable other problems that can occur in the sterilizing chamber. Moreover, chemical indicators which are attached to the tag or the sterile wrap travel with the instruments to provide the ultimate user with assurance that the instrument has been sterilized (or at least subject to conditions which normally would bring about sterilization).

The applicants assert that neither Ignacio nor Minerovic provide any motivation to move the chemical indicator of Ignacio from the sterilization chamber to the sterilant concentrate supply where conditions are expected to be different than they are in the sterilization chamber adjacent the goods. For example, as the water starts mixing with the powdered reagents, there will be an initial concentration spike which far exceeds the concentration in the sterilization chamber. The

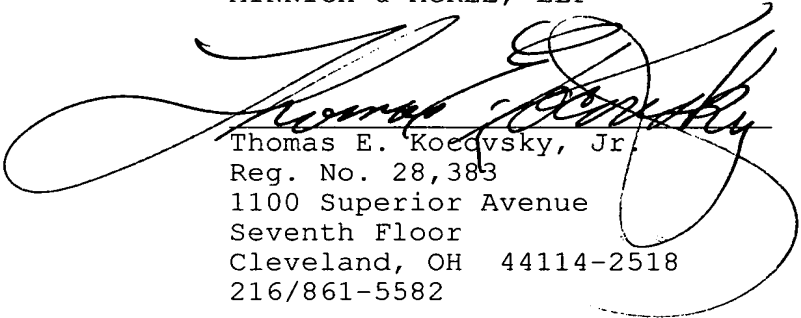
location of the water heater shows a difference in temperature is expected. The water also enters the mixing chamber first so that there will be sterilant solution in the mixing chamber for a different period of time than at an individual item, as well as different times at different temperatures and concentrations. Time, temperature, and concentration control the color change operation (col. 6, lines 1-4) of the Ignacio indicator.

The Examiner asserts that it is obvious to move the indicator of Ignacio; the applicants assert that the references provide no motivation to do so. It is believed that no amount of amendments to the claims will be able to resolve this basic disagreement between the applicants and the Examiner.

The applicants are enclosing a Supplemental Brief. For simplicity and to facilitate this appeal, the Supplemental Brief repeats all sections of the original Brief. Those sections which have been amended or added are marked in the left margin with an asterisk (\*). Hopefully, this will save the Board the inconvenience of switching back and forth between two documents.

Respectfully submitted,

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**CERTIFICATE OF MAILING**

I hereby certify that this **37 CFR § 1.93(b)(2) ELECTION** in connection with U.S. Patent Application **Serial No. 09/314,497** is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 20<sup>th</sup> day of June, 2003.

By: Nilary McNulty